

### REMARKS

In response to the office action dated June 17, 2008, Applicants amended claims 1-4, 9-10, 15, 17-19, 21-22, and 27-29, canceled claims 5, 8, and 34, and added claim 35-39. Claims 1-4, 6-7, 9-31, 33, and 35-39 are pending, with claims 6-7, 16, and 20 being provisionally withdrawn from consideration.

#### Claim Rejections -35 U.S.C. §102(b)

The Examiner rejected claims 1-3, 5, 8, 10-12, 15, 17-19, 22-24, and 27-28 under 35 U.S.C. §102(b) as being anticipated by Barath et al., US 5,112,305 ("Barath").

The Examiner also rejected claims 1, 2, 4-5, 15, 17-19, and 27-28 under 35 U.S.C. §102(b) as being anticipated by Vigil et al., US 5,713,863 ("Vigil").

As amended, claim 1 recites a balloon having a first compartment for containing a biological active material and a second compartment, without fluid communication with the first compartment, for receiving an inflation material to inflate the balloon.

Contrary to the balloon recited in claim 1, Barath's balloon defines a single balloon compartment that is used both for containing a fluid including a therapeutic agent and for receiving the fluid to inflate the balloon. Barath's balloon compartment receives the fluid containing the therapeutic agent from a catheter located in a shaft of the balloon to inflate the balloon and the received fluid causes an abrupt pressure increase in the balloon compartment to propel the fluid out of the compartment through holes on the surface of the balloon (e.g., at FIGS. 4 and 5, col. 2, line 65- col. 3, line 2, and col. 3, lines 34-40). Even if Barath's balloon shaft could be interpreted as a second compartment of his balloon, the balloon shaft is not separated from the balloon compartment in fluid communication, but rather includes side holes and allows the fluid delivered from the catheter to pass the holes of the balloon shaft and reach the balloon compartment (col. 2, line 65-col. 3, line 2). Accordingly, Barath did not describe and would not have made obvious Applicants' features of: "the balloon has a first compartment for containing the biologically active material and a second compartment, without fluid communication with

the first compartment, for receiving an inflation material to inflate the balloon,” as recited by claim 1.

Vigil described a flexible tube capable of expanding upon a translation movement of a grommet connected to a distal end of the tube and movable by a push-pull wire (FIGS. 3 and 4, and col. 6, lines 27-41). Vigil's flexible tube does not include an additional compartment without fluid communication with a compartment that is used for delivering a fluid medication to receive an inflation material to inflate the tube. There is no need to include such an additional compartment in Vigil's tube since his tube does not expand using an inflation material to be received in the tube, but rather expands using the mechanical movement of the attached grommet. Accordingly, Vigil did not describe and would not have made obvious Applicants' features of: “the balloon has a first compartment for containing the biologically active material and a second compartment, without fluid communication with the first compartment, for receiving an inflation material to inflate the balloon,” as recited by claim 1.

With respect to claim 15, neither Barath nor Vigil described or would have made obvious Applicants' features of: “sealed and rupturable micro-needles each having at least one spot that breaks upon triggering.”

Barath's tubular extensions on a balloon surface are not sealed but defines holes for fluid to be propelled from the balloon (col. 3, lines 8-9 and 38-40). Vigil's injectors are not sealed but have openings for a fluid medication to be injected into a vessel wall (abstract, FIGS. 5A-5B and 6A-6B). It would not have been obvious for one skilled in the art to replace Barath's tubular extensions or Vigil's injectors with sealed and rupturable micro-needles since one would not have known how to make such a replacement and whether such a replacement would allow Barath's and Vigil's apparatus to function as intended.

Claims 5 and 8 have been canceled. The dependent claims 2-4, 10-12, 17-19, and 22-24 are patentable over Barath or Vigil for at least the reasons discussed with respect to claims 1 and 15, from which they depend.

The rejections to claims 27-28 are addressed below.

### Claim Rejections - 35 U.S.C. §103(a)

The Examiner rejected claims 9-14 and 21-26 under 35 U.S.C. §103(a) as being unpatentable over Barath or Vigil in view of Yuzhakov, US 6,565,532 ("Yuzhakov").

Claims 9-14 depend from claim 1 and claims 21-26 depend from claim 15. As explained above, claims 1 and 15 are patentable over Barath and Vigil. Yuzhakov, like Barath or Vigil, did not describe and would not have made obvious Applicants' features of: "the balloon has a first compartment for containing the biologically active material and a second compartment, without fluid communication with the first compartment, for receiving an inflation material to inflate the balloon," as recited by claim 1 or "sealed and rupturable micro-needles each having at least one spot that breaks upon triggering," as recited by claim 15. Accordingly, claims 1 and 15 are patentable over Barath or Vigil in view of Yuzhakov. Claims 9-13, 14 and 21-26 are similarly patentable over Barath or Vigil in view of Yuzhakov for at least the reasons discussed with respect to claims 1 and 15.

### Allowable Subject Matter

Applicants acknowledge the Examiner's indication that claims 29-31 and 33 are allowed. Claim 29 has been amended to place the claim in a better form.

With respect to claim 34, which was subject to objection for depending from a rejected claim but indicated to contain patentable subject matter, Applicants have canceled claim 34 and amended claim 27 to include all the limitations of claim 34, thus placing claims 27-28 in condition of allowance.

All of the claims dependent from these claims are also patentable for at least similar reasons as those for the claims on which they depend are patentable.

Canceled claims, if any, have been canceled without prejudice or disclaimer.

Any circumstance in which the Applicants have (a) addressed certain comments of the Examiner does not mean that the Applicants concede other comments of the Examiner, (b) made arguments for the patentability of some claims does not mean that there are not other good reasons for patentability of those claims and other claims, or (c) amended or canceled a claim does not mean that the Applicants concede any of the Examiner's positions with respect to that claim or other claims.

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Respectfully submitted,

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